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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,855	03/17/2000	Hyun K. Kim	15280W003000	3023

20350 7590 09/26/2002

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EXAMINER

BADIO, BARBARA P

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 09/26/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/526,855

Applicant(s)

KIM ET AL.

Examiner

Barbara P Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 4,9-23,26-48 and 50-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,24,25 and 49 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: _____

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 19, 2002 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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4. Claims 1-3, 5-8, 24, 25 and 49 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 09/180,132. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to 17β -acyl- 11β -(4-substituted)phenyl compounds. For example, both applications encompass compounds wherein R^1 is $-N(CH_3)_2$, R^2 is halogen, alkyl or acyl, R^3 is alkyl, hydroxyl, alkoxy or acyloxy, R^4 is hydrogen or alkyl and X is $=O$ or $=N-OR^5$.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

w 5. Claims 1-3, 6-8 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Acosta et al.

Acosta et al. teach compounds such as 17α -hydroxy- 11β -(4-N, N-dimethylaminophenyl)19-norpregna-4,9-diene-3,20-dione, 17α -acetoxy- 11β -(4-N-dimethylaminophenyl)19-norpregna-4,9-diene-3,20-dione and 17α -hydroxy- 11β -(4-N-methylaminophenyl)19-norpregna-4,9-diene-3,20-dione (page 1985, compound #s 2, 3 and 4). The compounds taught by the reference are encompassed by the instant claims.

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6. Claims 1-3, 6-8 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Cook et al. ('548).

Cook et al. teach a genus of 17β -acetyl substituted compounds including 17α -ethynyl- 11β -(4-N,N-dimethylaminophenyl)19-norpregna-4,9-diene-3,20-dione and 17α -hydroxyl- 11β -(4-N,N-dimethylaminophenyl)19-norpregna-4,9-diene-3,20-dione (see the entire article, especially col. 3, line 45 – col. 4, line 43; col. 18, Table I, compound #4). The compounds and compositions taught by the reference are encompassed by the instant claims.

Claim Rejections - 35 USC § 103

7. The rejection of claims 1-3, 5-8, 24, 25 and 49 under 35 USC 103(a) over Scholz et al. ('886) is withdrawn.

8. The rejection of claims 1-3, 5-8, 24, 25 and 49 under 35 USC 103(a) over Peeters ('787) is maintained.

Applicant argues, both in the Remarks and Declaration by Dr. Kim, that the compounds exemplified and enabled by Peeters differ from the present invention in the stereochemistry at C-17 and activity possessed. Applicant's argument was considered but not persuasive for the following reasons.

The examiner disagrees that the stereochemistry at C-17 is inverted. According to the present specification, "alkyl" includes saturated or unsaturated hydrocarbon radicals (see page 5, lines 12-21 of the present specification) and, thus, the 17α -alkynes

substituent taught by Peeters is encompassed by the claimed invention and the compounds exemplified by the reference differ only in the exemplified substituent attached to the 17 β -position.

The reference teaches the R₅ (17 β) substituent is either hydroxyl or one of three groups, i.e., an acyloxy, alkoxy or acyl group having one to six carbon atoms (see col. 2, lines 35-38). The 17 β substituents taught by the reference are of a small group that each is readily envisaged by the ordinary artisan in the art making the 17 β -C1-C6 acyl derivatives of the exemplified compounds *prima facie* obvious. It is also noted that the reference is not limited to that which is exemplified but is evaluated based on the teachings as a whole.

Applicant also argues that unlike the prior art compounds, the claimed compounds possess antiprogestational activity with substantially less antiglucocorticoid activity. The examiner cannot make a determination since a side-by-side comparison of the prior art compounds and the claimed compounds was not provided. It is noted that the compounds compared should differ only in the 17 β substituents, i.e., comparison of the exemplified prior art compound and its 17 β -acetyl derivative as claimed by the present invention. In the absence of said comparison, applicant's argument of separation of properties is noted but not persuasive.

Lastly, applicant argues only one synthetic route is taught by the reference and that there is no indication of the production of the other isomer needed for production of the present invention. As stated above, the difference between the exemplified compounds and the claimed invention is in the exemplified 17 β -substituent and, thus,

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the issue of another isomer is not relevant. Also, the reference is a US patent and is enabled for the compounds disclosed therein. Applicant's argument of synthesis is not relevant to the patentability of the claimed compound since the ordinary artisan could obtain methods for producing the 17β acetyl compounds by doing a literature search. As shown in #s 5 and 6 above, 17β acetyl derivatives of the compounds taught by Peeters were known in the art and, thus, synthetic routes would be available to the skilled artisan.

For these reasons and those given in previous Office Actions, the rejection of claims 1-3, 5-8, 24, 25 and 49 under 35 USC 103(a) over Peeters ('787) is maintained.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P Badio, Ph.D. whose telephone number is 703-308-4595. The examiner can normally be reached on M-F from 7:30am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Barbara Padio
Barbara P Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB

September 25, 2002